Memorandum of Understanding

Meeting of the Vietnamese and United States Delegations in Follow-Up to the Joint Vietnam-US Scientific Conference on Human Health and Environmental Effects of Agent Orange/Dioxin
Hanoi, Vietnam
March 10, 2002

On March 3-6, 2002, the Vietnamese and United States Governments sponsored a scientific conference in Hanoi, Vietnam to exchange information on the health and environmental effects of Agent Orange and dioxin. This unique conference brought together scientists from Vietnam, the United States and 11 other countries to discuss the state-of-the-art of research into the health effects of dioxin. On the day following the conference, March 7, 2002, a select panel of international scientists identified data gaps in our understanding of the health and environmental effects of dioxin and recommended general areas of research in Vietnam that would help to fill these data gaps.

On Friday, March 8, 2002, senior scientists from the Vietnamese Ministry of Science, Technology and the Environment, the Vietnamese Ministry of Health, the US National Institute of Environmental Health Sciences, the US Environmental Protection Agency and the US Centers for Disease Control and Prevention met in Hanoi to establish an agreement for future research activities using the findings from the three-day conference and one-day workshop as a guide. The Vietnamese and US Government Agencies agreed to the following joint research plan.

Two major areas of research were addressed at the Hanoi conference: direct research on human health outcomes from exposure to dioxin and research on the environmental and ecological effects of dioxin and Agent Orange. In both of these areas, the workshop participants identified critical research needs; the highest priority areas are outlined below.

Areas of Research to be Developed

Priorities for Health Research

The primary concerns in Vietnam from prolonged exposure to dioxin are for reproductive and developmental disorders that may be occurring in the general population. The key areas for research in Vietnam include spontaneous abortions, miscarriage, premature birth, congenital malformations, endocrine disorders, neurological disorders, immunodeficiency, cancer, genetic damage and diabetes mellitus. US and Vietnamese scientists will review the available literature and set priorities for areas where both determine that the literature is insufficient to determine the presence or absence of a hazard and more research is needed.

Preliminary discussions have suggested two areas of research that should be further developed; research on existing populations with high exposures to dioxin relative to populations with low exposures (for example, people living near hotspots) and research on therapies to reduce dioxin body burdens in humans (such as some herbal therapies being proposed in Vietnam). Further discussions of this research should seriously

consider and be guided by the recommendations of the health scientists involved in the consultative workshop held on March 7, 2002 (attached as Annex 1).

Priorities for Environmental Research

Dioxin contaminants of Agent Orange have persisted in the environment in Vietnam for over thirty years. In addition to a better understanding of outcomes of exposure, an improved understanding of residue levels and rates of migration of dioxin and other chemicals in the environment is needed. "Hot spots" containing high levels of dioxin in soil have been identified and others are presumed to exist but have yet to be located. Dioxin has migrated through soil and has been transported through natural processes such as wind-blown dust and erosion into the aquatic environment. Contamination of soil and sediments provides a reservoir source of dioxin for direct and indirect exposure pathways for humans and wildlife. Movement of dioxin through the food web results in bioconcentration and biomagnification with potential ecological impacts and continuing human exposure.

Research is needed to develop approaches for more rapid and less expensive screening of dioxin residue levels in soil, sediment, and biological samples which can be applied in Vietnam. Improvements in this first step of analysis should be complemented by efforts to upgrade capabilities of laboratory facilities and equipment to international standards required by the research needs. These improved analytical capabilities can then be used to more readily determine locations of highly contaminated areas, monitor remediation and understand migration of dioxin in the natural environment. Monitoring efforts need to be linked to modeling efforts to understand fate and transport of dioxin in the environment. Innovative and cost-effective approaches to environmental remediation for application in Vietnam need to be developed, tested and applied. The environmental agencies of both countries strongly support the need for high quality research, development, and capacity building in these areas as a means to identify, characterize and mitigate dioxin ecological impacts and bridge knowledge gaps regarding human exposure both in the past and into the future. Coordination between health and environmental efforts will be necessary to achieve success in the efforts described above.

Preliminary discussions have suggested two areas of research that should be further developed: ecological and restoration research on a degraded upland forest (such as the Ma Da forest) and research on the identification, characterization and remediation of hot spots (such as Da Nang Airport). Further discussions of this research should seriously consider and be guided by the recommendations of the environmental scientists involved in the consultative workshop held on March 7, 2002 (attached as Annex 2).

Other Activities for the Development of Joint Research Collaborations

Any joint research effort between Vietnamese and US scientists on the health and environmental effects of Agent Orange/dioxin requires the development of long-term collaborations between scientists in both countries. In order to strengthen these collaborations, the following activities are needed:

1. Support and encourage the exchange of graduate and post-graduate trainees.
2. Support and encourage extended visits of senior scientists from both countries.

3. Develop and implement seminar series and training programs to support collaborations.

4. Provide support as needed to implement scientific exchange.

Process for Funding and Guiding Research

Both sides agree that no additional proposals or research will be conducted under this Memorandum of Understanding until the following tasks are completed:

1. Establishment of a Vietnam-US Joint Advisory Committee to:
   - Define the scope of the joint research program;
   - Coordinate the collaborative research program on human health and environmental effects of Agent Orange/Dioxin; and
   - Review and approve research content areas under the program.

   This coordinating body should have a support unit in each country and should meet at least once every year.

2. Development of regulations governing the organization and implementation of the collaborative research program in reference to and specification of relevant stipulations under the Agreement on Scientific and Technical Cooperation between the Government of the Socialist Republic of Vietnam and the Government of the United States of America and those under applicable laws in each country and international practices. In addition, formal agreements on the following issues must also be developed:
   - The methods by which research proposals are developed, evaluated and funded;
   - The eligibility criteria for scientists wishing to be included in this research;
   - The applicable scientific and ethical policies to which the joint research must comply;
   - The methods for evaluating compliance with applicable laws, regulations and policies and the frequency in which compliance is reviewed;
   - The degree to which research findings will be made available to the international scientific community; and
   - The avenues through which research findings will be published and the process that must be followed for publication approval.

3. Funding resources and funding mechanisms are established to ensure the success of the research effort. These include sufficient funding for the core research effort, for human resources development, and for laboratory facilities and equipment.

This document comprises one memorandum of understanding and three Annexes: 1) Agent Orange/Dioxin Research Gaps Workshop on Health Effects; 2) Agent Orange/Dioxin Research Gaps Workshop on Environment; 3) List of participants from discussions on March 7 and March 8.

Signed in Hanoi on the 10th day of March 2002.

Dr Anne P. Sassaman
Director, Division of Extramural Research and Training
National Institute of Environmental Health Sciences
National Institutes of Health
Department of Health and Human Services
For the U. S. side

Dr. Nguyen Ngoc Sinh
Director General
National Environmental Agency
Ministry of Science, Technology and Environment
For the Vietnamese side

Attachments: Annex 1, Annex 2, Annex 3

ANNEX 1: Agent Orange/Dioxin Research Gaps Workshop on Health Effects

Hanoi, Vietnam, March 7, 2002
Recommendations from the Scientists' Workshop to the Organizing Committee
On a Proposed Framework of Areas for Joint Activities

On March 7, 2002, a group of scientists from Vietnam, the US and other nations met to recommend research projects to the US and Vietnamese Governments. These recommendations are given below and represent the consensus opinion of the scientists present at the meeting. It does not necessarily reflect the policy of either nation.

Introduction

The session participants were reminded of the goals of the day's activity and the conclusions of the conference sessions conducted over the past three days. The joint statement was distributed to members for orientation.

Members of the session introduced themselves and indicated their expertise and interest in particular health effects areas. Topics of concern for research opportunities and gaps were then summarized. Based on this discussion, the members of the session agreed to focus their discussion and provide recommendations to the Joint Organizing Committee in four specific areas:

- Dissemination of existing data and findings between U.S. and Vietnam scientists
- Training programs to enhance collaboration between U.S. and Vietnam scientists
- Short term opportunities
- Long term opportunities

Dissemination of existing data and findings between U.S. and Vietnam scientists

Members of the session agreed that special effort to publish the proceedings of the meeting as well as the creation of data resources for all interested scientists should be given high priority. Of special concern was the translation and dissemination of materials prepared by Vietnam scientists for the 10/80 Committee and 33 Committee, as that material would be of interest to scientists both within Vietnam and in the U.S. Opportunities for publication exist within *Environmental Health Perspectives* as well as various web site locations. Federal agencies may want to charge several of the organizing committee members with the development of an agenda for topics for rapid paper or web-based publication.

Training programs to enhance collaboration between U.S. and Vietnam scientists

There are differences in research practices, health data, health care systems and technology available for research in the U.S. and Vietnam. Because of these differences,

it is essential to take advantage of existing and potential new training opportunities to enhance collaboration. The Fogarty International Program was cited as an example of an existing training mechanism which would allow for training opportunities. Opportunities to have U.S. staff work through the Hanoi School of Public Health should be explored. Creating opportunities for the exchange of young scientists and providing training in a broad range of areas was emphasized.

Short term opportunities

The health session members agreed that these should be completed within a year or have achieved substantial progress within a year.

- Institutional Review Board capability -- members agreed that an urgent priority should focus on the development of Institutional Review Board (IRB) capabilities within the health centers of Vietnam to facilitate participation in research opportunities and collaborations with U.S. investigators. While the process was not discussed extensively, one potential mechanism may be to bring the National Institutes of Health (NIH) staff to Vietnam to conduct workshops on research ethics as established in the U.S. (taking those workshops as an opportunity to promote pairing of U.S. and Vietnam scientists to further facilitate collaborative possibilities).
- Planning grants -- the members agreed that the Federal agencies from both governments should explore rapidly the development of planning grants. These grants would support an investigator from the U.S. and an investigator from Vietnam to establish a collaboration and begin feasibility studies and planning for a formal grant. Funds would support travel and communication for both investigators for a period of 24-36 months while they develop a formal grant application to the U.S. National Institutes of Health.
- Principles for interactions and collaboration -- there is a need to develop guiding principles for interactions between U.S. and Vietnamese investigators.
- Criteria for site selection for population studies -- while there is a clear interest in hot spots (i.e., highly contaminated areas), they should not be the only sites of interest, and guiding criteria for evaluation of proposed sites need to be developed jointly by the U.S. and Vietnamese governments.
- Yearly scientific meetings for collaborators and potential collaborators -- select relevant themes to highlight beyond presentation of research results (e.g., IRB issues, research design issues).

Long term opportunities

- Birth cohort study -- similar to that being conducted in Denmark and planned in the U.S.
- Health effects surveillance systems which allow GIS and spatial disease monitoring, modeling and tracking.
- Clinical trials which include prevention research.

- Research linking health and environmental research.
- Development of collaborative population research based on appropriate disease categories; endometriosis, trophoblastic disease, neural tube defects.
- Enhance vital records systems -- birth registration, death certificates, census data, etc.

Annex 2: Agent Orange/Dioxin Research Gaps Workshop on Environment

Hanoi, Vietnam, March 7, 2002
Recommendations from the Scientists' Workshop to the Organizing Committee
On a Proposed Framework of Areas for Joint Activities

On March 7, 2002, a group of scientists from Vietnam, the U.S. and other nations met to recommend research projects to the U.S. and Vietnamese Governments. These recommendations are given below and represent the consensus opinion of the scientists present at the meeting. It does not necessarily reflect the policy of either nation.

Recommendations from the group:

Joint environmental research activities of the U.S. and Vietnam should include, as appropriate, aspects of the following research areas:

- Analytical research, including research into detection and assessment of "hot spots," areas of high contamination.
- Fate and transport studies to estimate potential routes of exposure and assist in characterizing risk.
- Remediation studies to develop optimal technologies for removing hazardous contaminants.
- Ecosystem restoration research, focusing initially on upland forests but eventually including mangroves and aquatic ecosystems.
- All these ecological/environmental research activities will be supported by appropriate capacity building, including scientific information transfer, information technology, equipment, training (especially of young investigators), and support for collaborations.

Vietnamese scientists proposed the use of two model demonstration sites for research activities: Da Nang airport and Ma Da forest. These sites are proposed both because of their usefulness as models of the environmental effects and because they are more easily accessible than other affected sites are. The environmental effects at these two sites are very different, as noted below. The U.S. scientists endorsed the idea of demonstration sites but said they would defer to the Vietnamese scientists for the choice of the specific sites.

Da Nang airport is an example of a highly exposed area. It was used as a military base during the war. There are many people living nearby whose water supply is compromised by hazardous contamination. Vietnamese scientists would suggest collaboration on projects to assess and remediate an area near Da Nang airport as a model for how such technologies could work. The most highly contaminated portion of the site, which will be the focus of decontamination activities, is about one hectare. Note: Da Nang airport is currently being used as a commercial airport, so research activities would have to be conducted around ongoing commercial activity. Vietnamese authorities will

have to be consulted to make sure activities on the contaminated area are kept separated from any human contact. The contaminated area is close by the airport, but it is isolated from it.

Ma Da is an example of a degraded upland forest. The site is located near Ho Chi Minh City. This demonstration site would be used to test ecosystem restoration strategies as opposed to remediation of contamination, since the forest is not at this time very much contaminated. The problem with this site is ecosystem impact from deforestation rather than residual chemical contamination. Many attempts at restoration have been made which have not met with success. It is difficult to restore inland areas in which the soil has been degraded.

In addition, there was discussion of focusing research on the impacts of defoliation on the mangroves and how best to effect their recovery. There are concerns about the mangroves because they are a semi-aquatic system. They are also very important for the overall ecology. These are not, however, the first priority for the Vietnamese scientists. They might be selected as a third priority area if resources permit.

Research Plan for Da Nang site

The ultimate objective for the research and workplan for the Da Nang site is a feasible level of decontamination side-by-side with research on decontamination/remediation technologies, on fate and transport of dioxins, and on effects on flora and fauna in the area.

Analytical research: Investigation of different ways to measure dioxin and other chemical components of herbicides and their metabolites is needed.

Da Nang demonstration project will need site characterization to help select correct approaches for remediation. Criteria for decontamination will need to be established.

Fate and transport: The effects of the patterns of water flow through this site during rainy season will necessitate studies of fate and transport of dioxin and other contaminants into streams and rivers. Ecological impacts, including impacts on biodiversity, should be evaluated.

Remediation research: Remediation technology research projects will need to be developed for Da Nang. It is critically important that trained personnel be made available to carry out this work to avoid injury to workers. The remediation and site characterization should be conducted along the most stringent guidelines, training and equipment for protection of workers.

In addition, many people live near the Da Nang site. It may be possible to coordinate research on human health effects of Agent Orange/dioxin with environmental research at this site.

Research Plan for Ma Da site

The ultimate objective for the research and workplan for the Ma Da site is restoration of the deforested area to a state that will promote the development of a tropical forest ecosystem.

Analytical research: Ma Da demonstration project will have a need for site characterization.

Ecosystem research: A two-pronged approach was proposed. This would include side-by-side efforts to do research projects on small areas and to attempt actual restoration at the same time on larger adjacent areas.

The Dong Nai river ecosystem is also important to consider in planning ecosystem research on the Ma Da forest.

In Ma Da forest, restoration has been initiated, but there is a question about whether the appropriate species have been used.

There are issues about ecosystem restoration in terms of what will be feasible. Many deforested sites have been invaded by grass and bamboo, which are impervious to herbicides. Burning the vegetation presents its own environmental problems. This issue will require careful consideration. It may be that an intermediate type of restoration could be the focus for initial efforts, rather than attempting to reconstruct the original ecosystem. Research on ecological succession is needed.

If resources are available, it is important for these two research projects to go forward in parallel, with coordination and collaboration where necessary. There were no other known constraints that would prevent the two projects going forward together.

An interdisciplinary program was proposed as a model for joint activities. Such a program would support research teams focusing on analytical activities, fate and transport studies, development of remediation technologies, etc. Specific parts of the projects would focus on providing training and instrumentation. It was also recommended that studies take into account the needs and activities of health scientists and epidemiologists in order to ensure that health effects research and environmental research is optimally coordinated.

Annex 3: List of Participants

March 7, 2002 Discussion, Workshop on Health

U.S. Participants

1) Dr. Thomas Sinks, Centers for Disease Control and Prevention
2) Dr. Allan Smith, University of California, Berkeley
3) Dr. David Carpenter, State University of New York, Albany
4) Dr. Lutz Edler, German Cancer Research Center
5) Dr. Irva Hertz-Piccioto, University of California, Davis
6) Dr. Drue Barrett, Centers for Disease Control and Prevention
7) Dr. Michael Linnan, Health Attache, U.S. Embassy to Hanoi
8) Dr. Brenda Eskenazi, University of California, Berkeley
9) Dr. Paolo Toniolo, New York University
10) Dr. Long Ngo, Harvard University
11) Dr. Donald Mattison, Columbia University School of Public Health

Vietnamese Participants

1) Prof. Hoang Dinh Cau, Former Chairman of 10/80 Committee
2) Prof. Bui Dai, Former Director of Hospital 108
3) Prof. Phan Thi Phi Phi, Hanoi Medical College
4) Prof. Trinh Van Bao, Hanoi Medical College
5) Dr. Nguyen Thi Ngoc Phuong, Director, Tu Du Hospital
6) Prof. Nguyen Van Nguyen, Army Academy
7) Prof. Truong Dinh Kiet, Institute of Medicine and Pharmacology, Ho Chi Minh City
8) Prof. Le Bach Quang, Army Academy
9) Dr. Nguyen Phu Thang, Polio Clinic, Hue Province
10) Dr. Chu Quoc Truong, Army Academy

Annex 3 (Continued)

March 7, 2002 Discussion, Workshop on Environment

U.S. Participants

1) Dr. Vance Fong, U.S. Environmental Protection Agency
2) Dr. Arthur Galston, Yale University
3) Dr. John Geisy, Michigan State University
4) Dr. Sheila Newton, National Institute of Environmental Health Sciences
5) Dr. Dennis Paustenbach, Exponent, Inc.
6) Dr. M. B. Ray, National University of Singapore
7) Mr. Gary Sigmon, U.S. Embassy, Hanoi
8) Dr. Jeanne Stellman, Columbia University
9) Dr. William Suk, National Institute of Environmental Health Sciences
10) Dr. William Farland, U.S. Environmental Protection Agency

Vietnamese Participants

1) Prof. Dang Vu Minh, National Center for Natural Science and Technology
2) Prof. Vo Quy, Vietnam National Institute
3) Prof. Dang Huy Huynh, Environmental Resources Protection Association
4) Prof. Tran Xuan Thu, Joint Vietnam-Russian Tropical Center
5) Prof. Chu Pham Ngoc Son, Analytical Environmental Service Center
6) Prof. Nguyen Duc Hue, Hanoi National Institute
7) Dr. Nguyen Van Minh, Environmental Treatment Center
8) Dr. Dang Thi Cam Ha, National Center for Natural Science and Technology
9) Eng. Phung Tuu Boi, forest Investment and Planning Institute

Annex 3 (Continued)

March 8, 2002 Discussion

U.S. Delegation

1) Dr. Anne Sassaman, National Institute of Environmental Sciences
2) Dr. Christopher Portier, National Institute of Environmental Sciences
3) Dr. William Farland, U.S. Environmental Protection Agency
4) Dr. Drue Barrett, Centers for Disease Control and Prevention
5) Mr. Gary Sigmon, U.S. Embassy, Hanoi
6) Dr. Joel Michalek, Department of Defense
7) Dr. Larry Needham, Centers for Disease Control and Prevention
8) Dr. Michael Linnan, Health Attache, U.S. Embassy, Hanoi
9) Mrs. Sandra Lange, National Institute of Environmental Sciences
10) Dr. Sheila Newton, National Institute of Environmental Sciences
11) Dr. Thomas Sinks, Centers for Disease Control and Prevention
12) Mr. Vance Fong, U.S. Environmental Protection Agency
13) Dr. William Suk, National Institute of Environmental Sciences

Vietnamese Delegation

1) Dr. Nguyen Van Tuong, Ministry of Health
2) Dr. Nguyen Ngoc Sinh, Ministry of Science, Technology and Environment
3) Prof. Trinh Van Bao, Ministry of Health
4) Eng. Phung Tuu Boi, Ministry of Agriculture and Rural Development
5) Dr. Nguyen Tien Dung, Ministry of Science, Technology and Environment
6) Dr. Dang Thi Cam Ha, National Center for Natural Science and Technology
7) Dr. Tran Manh Hung, Ministry of Health
8) Prof. Phan Thi Phi Phi, Ministry of Health
9) Dr. Vo Quy, Hanoi University